



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Bruno DE LIGNIERES
Title: TREATMENT OF MASTALGIA WITH
4-HYDROXY TAMOXIFEN
Appl. No.: 10/734,640
Filing Date: 12/15/2003
Examiner: Unassigned
Art Unit: 1614

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

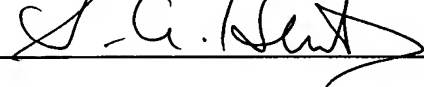
All of the documents are in English.

Applicant respectfully requests that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

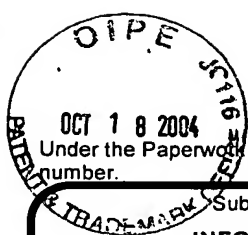
Respectfully submitted,

Date 18 October 2004

By 

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Attorney for Applicant
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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Date Submitted: October 18, 2004

(use as many sheets as necessary)

Sheet 1 of 4

Complete if Known

Application Number 10/734,640
Filing Date 12/15/2003
First Named Inventor Bruno DE LIGNIERES
Group Art Unit 1614
Examiner Name Not yet assigned
Attorney Docket Number 029488-0111

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			
	A1	4,919,937		Pierre Mauvais-Jarvis	4/24/1990	

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A2	J. BARRAT et al., "Effet <i>in vivo</i> de l'administration locale de progestérone sur l'activité mitotique des galactophores humains", J. Gynecol. Obstet. Biol. Reprod. 19: 269-274 1990.	
	A3	Bronaugh & Maibach, "Percutaneous Absorption Drugs-Cosmetics-Mechanisms-Methodology", Marcel Dekker Inc., New York, 1999.	
	A4	Philip CARTHEW et al., "Cumulative exposure to tamoxifen: DNA adducts and liver cancer in the rat", Arch Toxicol (2001) 75: 375-380.	
	A5	Gerard CHETRITTE et al., "Effect of Promegestone, Tamoxifen, 4-Hydroxytamoxifen and ICI 164,384 on the Oestrone Sulphatase Activity of Human Breast Cancer Cells", Anticancer Research 13: 931-934 (1993).	
	A6	Eric C. DIETZE et al., "Tamoxifen but Not 4-Hydroxytamoxifen Initiates Apoptosis in p53(-) Normal Human Mammary Epithelial Cells by Inducing Mitochondrial Depolarization", The Journal of Biological Chemistry Vol. 276, No. 7, Issue of February 16, 2001, pp. 5384-5394.	

Examiner Signature

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: October 18, 2004 (use as many sheets as necessary)		Application Number	10/734,640
		Filing Date	12/15/2003
		First Named Inventor	Bruno DE LIGNIERES
		Group Art Unit	1614
		Examiner Name	Not yet assigned
		Attorney Docket Number	029488-0111
Sheet	2	of	4

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
	A7	Ian S. FENTIMAN, "Tamoxifen and Mastalgia an Emerging Indication", Drugs, Vol. 32, No. 6, December 1986, pp. 477-480.	
	A8	I.S. FENTIMAN et al., "Dosage and duration of tamoxifen treatment for mastalgia: a controlled trial", BR. J. SURG. September 1988, Vol. 75, No. 9, pp. 845-846.	
	A9	I.S. FENTIMAN et al., "Studies of tamoxifen in women with mastalgia*", The British Journal of Clinical Practice, Supplement 68, Vol. 43, No. 11, November 1989, pp. 34-36.	
	A10	N. GIAMBIAGI et al., "IMMUNOLOGICAL DIFFERENCES BETWEEN THE ESTRADIOL-, TAMXIFEN- AND 4-HYDROXY-TAMOXIFEN-ESTROGEN RECEPTOR COMPLEXES DETECTED BY TWO MONOCLONAL ANTIBODIES", J. Steroid Biochem. Vol. 30, No. 1-6, pp. 213-217, 1988.	
	A11	IBIS investigators, "First results from the International Breast Cancer Intervention Study (IBIS-I): a randomised prevention trial", The Lancet, Vol. 360, September 14, 2002, pp. 817-824.	
	A12	V. Craig JORDAN et al., "Metabolites of tamoxifen in animals and man: identification, pharmacology, and significance", Breast Cancer Research and Treatment, 2, pp. 123-138.	
	A13	George G.J.M. KUIPER et al., "Comparison of the Ligand Binding Specificity and Transcript Tissue Distribution of Estrogen Receptors α and β ", Endocrinology, Vol. 138, No. 3, 1997, pp. 863-870.	
	A14	Frédérique KUTTENN et al., "MÉDECINE ET THÉRAPEUTIQUE", C.R. Acad. Sc. Paris, , Série III, No. 12, 1985, 300:457-461.	
	A15	Catherine MALET et al., "Tamoxifen and Hydroxytamoxifen Isomers <i>versus</i> Estradiol Effects on Normal Human Breast Cells in Culture", Cancer Research, Vol. 48, No. 24, December 15, 1988, pp. 7193-7199.	

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	A16	Pierre MAUVAIS-JARVIS et al., "trans-4-Hydroxytamoxifen Concentration and Metabolism after Local Percutaneous Administration to Human Breast", Cancer Research, Vol. 46, March 1986, pp. 1521-1525.	
	A17	Henri PUJOL et al., "Phase I Study of percutaneous 4-hydroxy-tamoxifen with analyses of 4-hydroxy-tamoxifen concentrations in breast cancer and normal breast tissue", Cancer Chemother. Pharmacol., 36:493-498 (1995).	
	A18	David W. ROBERTSON et al., "Synthesis of the E and Z Isomers of the Antiestrogen Tamoxifen and Its Metabolite, Hydroxytamoxifen, in Tritium-Labeled Form", J. Org. Chem., 1982, Vol. 47, No. 12, pp. 2387-2393.	
	A19	David W. ROBERTSON et al., "TAMOXIFEN ANTIESTROGENS, A COMPARISON OF THE ACTIVITY, PHARMACOKINETICS, AND METABOLIC ACTIVATION OF THE C/S AND TRANS ISOMERS OF TAMOXIFEN" Journal of Steroid Biochemistry, Vol. 16, pp. 1-13, (1982).	
	A20	Fabrice SAUVEZ et al., "Cutaneously applied 4-hydroxytamoxifen is not carcinogenic in female rats", Carcinogenesis Vol. 20, No. 5, pp. 843-850 1999.	
	A21	John N. WOLFE MD, "RISK FOR BREAST CANCER DEVELOPMENT DETERMINED BY MAMMOGRAPHIC PARENCHYMAL PATTERN", Cancer, May 1976, Vol. 37, No. 5, pp. 2486-2492.	
	A22	Deborah N. ADER PhD, et al., "Prevalence and impact of cyclic mastalgia in a United States clinic-based sample", Am. J. Obstet. Gynecol., Vol. 177, No. 1, pp. 126-132, July 1997.	
	A23	M.R. CALLANTINE PhD. et al., "Micronized 17 β -Estradiol for Oral Estrogen Therapy in Menopausal Women", Obstetrics & Gynecology Vol. 46, No. 1, July 1975, pp. 37-41.	
	A24	A. GORINS et al., "A FRENCH DOUBLE-BLIND CROSSOVER STUDY (DANAZOL VERSUS PLACEBO) IN THE TREATMENT OF SEVERE FIBROCYSTIC BREAST DISEASE", Eur. J. Gynaec. Oncol. Vol. 2, 1984, pp. 85-89.	
	A25	S.J. Graham PhD, "Changes in Fibroglandular Volume and Water Content of Breast Tissue During the Menstrual Cycle Observed by MR Imaging at 1.5 T", JMRI, Vol. 5, No. 6, November/December 1995, pp. 695-701.	

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	A26	R.E. MANSEL et al., "A Double Blind Trial of the Prolactin Inhibitor Bromocriptine in Painful Benign Breast Disease", Br. J. Surg. Vol. 65, (1978), pp. 724-727.	
	A27	Catherine S. MURPHY et al., "Structure-Function Relationships of Hydroxylated Metabolites of Tamoxifen that Control the Proliferation of Estrogen-Responsive T47D Breast Cancer Cells In Vitro", Molecular Pharmacology, 38, pp. 737-743, (1990).	
	A28	Lawrence H. BLOCK, PhD, "Epidermal and Transdermal Drug Delivery", Medicated Topicals, Chapter 44, Remington: The Science and Practice of Pharmacy, Alfonso R. Gennaro, Lippincott Williams and Wilkins, 2000, pp. 836-858.	
	A29	M. SAMBROOK et al., "Ultrasonic Doppler Study of the Hormonal Response of Blood Flow in the Normal Human Breast", Ultrasound In Med. & Biol. Vol. 13, No. 3, pp. 121-129 (1987).	

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